

REMARKS

Filed concurrently herewith is a request for a two-month extension of time, which extends the shortened statutory period for response to September 17, 2003. Accordingly, it is respectfully submitted that Applicants' response is being timely filed.

The Official Action dated April 17, 2003 has been received and its contents carefully noted. In view thereof, claims 1-13 and 30-36 have been canceled in their entirety without prejudice nor disclaimer of the subject matter set forth therein, and claims 14-29, 37 and 38 have been amended in order to better define that which Applicants regards as the invention. Accordingly, claims 14-29 and 37-41 are presently pending in the instant application.

With reference now to the Official Action, particularly page 2 thereof, claim 14 has been essentially objected to as including minor informalities. Particularly, the Examiner has noted that the preamble is awkward and has suggested a proposed amendment for overcoming this objection. In this regard, as can be seen from the foregoing amendments, claims 14, 22 and 37 have been amended in order to more clearly define that which Applicants regard as the invention. Accordingly, it is respectfully submitted that Applicants' claimed invention as set forth in claims 14-29 and 37-41 is now in proper formal condition for allowance.

Further on page 2 of the Office Action, claims 14-29, 37-41 have been rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 4,097,237, issued to Oberhardt et al. or U.S. Patent No. 4,683,223, issued to Trivedi. These rejections are respectfully traversed in that neither the patent to Oberhardt et al. nor that of Trivedi disclose or remotely suggest that which is presently set forth by Applicants' claimed invention.

Initially, as the Examiner can readily appreciate, the present invention is directed to and independent claim 14 recites a method of preparing a sample for quantification from a biological sample with a method comprising a step of mixing an unknown volume of biological sample collected without quantifying a volume thereof with a specified volume of an aqueous solution. Independent claim 22 recites a method of quantifying elements to be quantified in a biological sample with a method comprising a step of mixing an unknown volume of biological sample collected without quantifying a volume thereof with a specific volume of an aqueous solution containing a specified amount of indicating material while independent claim 37 recites a method of quantifying elements to be quantified in a

biological sample comprising the steps of preparing a sample for quantification composed of an unknown volume of biological sample containing elements to be quantified and a specified volume of aqueous solution containing a specified amount of indicating material, determining a dilution ratio of the biological sample from a concentration of the indicating material in the specified volume of aqueous solution, determining a concentration of the elements to be quantified in the sample for quantification and determining the elements to be quantified in the biological sample based on the dilution ratio of the biological sample. As will be discussed in greater detail herein below, neither the Oberhardt et al. nor Trivedi reference disclose nor remotely suggest that which is presently set forth by Applicants' claimed invention.

Specifically, in reviewing the teachings of Oberhardt et al., it is noted that the Examiner states on page 2 of the Office Action that:

"Oberhardt et al. (USP, 4,097,237) teaching column 1 lines 13+ that it is known to add a known volume of dye to an unknown volume of blood."

To the contrary, however in reviewing the Oberhardt et al. reference, it is noted that the portion of the reference referred to by the Examiner, particularly, lines 15-18 of the Oberhardt et al. reference, actually describes that:

"The colorimetric technique disclosed by Ponder comprises the addition of a known volume of dye at a known concentration to a known (*emphasis added*) volume of blood sample of unknown cell volume."

Accordingly, while the Examiner has stated that Oberhardt et al. teaches that is known to add a known volume of dye to an unknown volume of blood, this is clearly not the case in accordance with the teachings of Oberhardt et al. wherein the reference specifically states adding a known volume of dye at a known concentration to a known volume of a blood sample. The blood sample may include an unknown cell volume, however, the reference clearly teaches one of ordinary skill in the art to add a known volume of dye at a known concentration to a known volume of a blood sample rather than an unknown volume of a biological sample as is the case with Applicants' present invention. Accordingly, it is respectfully submitted that Applicants' claimed invention as set forth in claims 14-29 and 37-41 clearly distinguishes over the teachings of Oberhardt et al. and is in proper condition for

allowance.

With respect to the teachings of Trivedi, a review of this reference, particularly the portion of the reference noted by the Examiner reveals that Trivedi sets forth that:

“The remaining exudates phenol red mixture is centrifuged at 750xg for 15 minutes. One hundred μ l of the supernatant fluid is diluted with 3.9ml of phosphate buffer and the absorbance is measured at 560nm.”

As one of ordinary skill in the art would readily understand from this portion of the disclosure, in Trivedi, the sample amount is known, that is one hundred μ l of the supernatant fluid is mixed (diluted) with a known dye (3.9 ml of phosphate buffer). Specifically, in the formula for calculating the exudate volume (V1) of Trivedi, all the values other than the exudates volume (V1) must be known including (A3) which apparently corresponds to the volume of the supernatant fluid.

Consequently, while the Examiner has stated that:

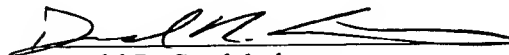
“Trivedi (USP 4,683,223) teach in column 13, lines 19+ addition of 2ml of a phenol red solution to an unknown volume of exudates and a method for determination of the volume of the unknown exudates.”

It is Applicants' position that Trivedi neither discloses nor remotely suggest the “addition of 2ml of a phenol red solution to an unknown volume exudates,” but rather discloses “additional of 2ml of a phenol red solution to a known volume exudates (one hundred μ l of the supernatant fluid). Accordingly, because there is no disclosure nor remote suggestion of mixing an unknown volume of biological sample collected without quantifying a volume thereof with a specified volume of an aqueous solution in order to quantify elements to be quantified in the biological sample set forth by Trivedi, it is respectfully submitted that Applicants' claimed invention clearly distinguishes over the teachings of Trivedi and is neither anticipated by, nor rendered obvious in view of the disclosure of Trivedi.

Therefore, in view of the foregoing, it is respectfully requested that the objections and rejections of record be reconsidered and withdrawn by the Examiner, that claims 14-29 and 37-41 be allowed and that the application be passed to issue.

Should the Examiner believe a conference would be of benefit in expediting the prosecution of the instant application, he is hereby invited to telephone counsel to arrange such a conference.

Respectfully submitted,



Donald R. Studebaker
Registration No. 32,815

NIXON PEABODY LLP
Suite 900, 401 9th Street, N.W.
Washington, D.C. 20004-2128
(202) 585-8000